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OFFICE OF PREVENTION, PESTICIDES  
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HEALTH EFFECTS DIVISION  
SCIENTIFIC DATA REVIEWS  
EPA SERIES 361

**MEMORANDUM**

Date: 4/17/2008

**SUBJECT:** **Ingredient:** Thifensulfuron Methyl **Title:** Label Amendments and Petition for Tolerances on Wheat Forage and Hay, Oat Forage and Hay, and Barley Hay.

PC Code: 128845	DP Barcode: 350544
Decision No.: 379517	Registration Nos.: 352-446, 352-714, 352-610
Petition No.: 7F7219	Regulatory Action: Section 3
Risk Assess Type: Single Chemical/Aggregate	Case No.: None
TXR No.: None	CAS No.: 79227-27-3
MRID Nos.: 47138301, 47138302, 47138303	40 CFR: 180.439

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E.I. DuPont de Nemours and Company, the registrant of thifensulfuron methyl, has proposed amending the current use directions for barley, oats, and wheat, to allow for the harvest of hay and forage. Currently there are label restrictions against the feeding of treated commodities to livestock. In support of the tolerance petition, DuPont submitted field trial data for oat forage and hay, wheat forage and hay, and barley hay.

*Rec'd in file  
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## Background

Thifensulfuron methyl (methyl 3-[[[[(4-methoxy-6-methyl-1,3,5- triazin-2-yl)amino] carbonyl]amino] sulfonyl]-2-thiophenecarboxylate) is a sulfonylurea herbicide (Group 2) registered for postemergence application to barley, canola, cotton, flax, field corn, oats, soybeans, and wheat for selective control of broadleaf weeds. It is also registered for use as a preemergence burndown broadcast application to wheat, barley, oats, soybeans, and field corn, and as a preplant burndown application to canola, cotton, rice, grain sorghum, and sugar beets.

There are currently ten end-use products (EPs) containing thifensulfuron methyl registered to DuPont for pre- and postemergence uses on barley, oats, and wheat. These EPs are formulated as either dry flowables or water soluble granules, and contain 4.7-75% thifensulfuron methyl. Two of these EPs, a 75% DF and 50% SG, contain only thifensulfuron methyl, while the remaining EPs are mixtures of thifensulfuron methyl with tribenuron methyl, metsulfuron methyl, and/or dicamba. Three example labels were provided with the proposed revisions, including a 75% DF (EPA Reg. No 352-446) and two multiple active ingredient formulations, a 33.3% SG (EPA Reg. No 352-714) and a 37.5% DF (EPA Reg. No 352-610). The registered uses allow for up to two postemergence broadcast applications to barley and wheat prior to flag leaf emergence at rates totaling 0.05 lb ai/A, and for a single broadcast postemergence application to oats prior to flag leaf emergence at up to 0.019 lb a.i./A. Preemergence applications are also allowed on all three crops, but the maximum total seasonal rate is 0.05 lb ai/A.

For all three crops, the proposed pre-harvest interval (PHI) is 7 days for forage and 30 days for hay. In conjunction with these label amendments, DuPont is proposing the following permanent tolerances for thifensulfuron methyl:

Barley, hay.....	0.7 ppm
Oat, forage.....	0.2 pm
Oat, hay .....	2.0 ppm
Wheat, forage .....	1.0 ppm
Wheat, hay.....	0.8 ppm

Permanent tolerances are currently established for residues of thifensulfuron methyl in/on barley, canola, corn, cotton, flax, oat, rice, sorghum, soybean, and wheat commodities ranging from 0.02 to 0.10 ppm [40 CFR§ 180.439 (a)]. No tolerances are established for residues in either animal commodities or rotational crops.

The most recent human health risk assessment for thifensulfuron methyl was performed in December 2006 (Memo, D. Dotson, D332697, 12/12/2006). As stated above, the current petition is for the lifting of a feeding restriction. This label change results in no changes in the exposure or risk estimates reported in the previous risk assessment. Reference may be made to the previous risk assessment for the exposure and risk estimates that result from the registered and proposed uses of thifensulfuron methyl. The dietary exposure and risk estimates are listed in Table 1, below. The aggregate exposure and risk estimates are discussed below as well.

The exposure and risk estimates reported in the previous risk assessment do not change for the following four reasons: 1) no changes are being made to any of the tolerances for human food items, 2) HED is not recommending in favor of tolerances for animal commodities because these tolerances are not needed even with the new feed items, 3) as a result of the fact that thifensulfuron methyl is not being registered on any additional crops, there is no change in the estimated drinking water concentrations of the herbicide, and 4) no residential uses are being proposed.

Reference may be made to the previous risk assessment for a discussion of the hazard characterization, FQPA considerations, tolerance enforcement methods, exposure and risk estimates, drinking water residue profile, and occupational exposure estimates associated with the use of thifensulfuron methyl. This previous risk assessment also contains the toxicology profile table and the toxicological endpoint table.

### **Data Deficiencies and Regulatory Recommendations**

No major deficiencies were noted in the subject petition that would preclude establishing permanent tolerances for residues of thifensulfuron methyl on the proposed commodities. The available field trial data are adequate and support the 7 and 30 day PHIs being proposed for forage and hay. HED recommends in favor of establishing permanent tolerances for thifensulfuron methyl at 0.8 ppm on barley hay, 0.2 ppm on oat forage, 0.05 ppm on oat hay, 2.5 ppm on wheat forage, and 0.7 ppm on wheat hay. However, the deficiencies listed below should be resolved.

- Labels for all EPs containing postemergence uses of thifensulfuron methyl on wheat, barley, or oats need to be amended to specify minimum PHIs of 7 days for forage and 30 days for hay. In addition, the label for the 37.5% dry flowable (EPA Reg. No. 352-610) should be clarified to indicate minimum PHIs of 7 days for forage, 30 days for hay, and 45 days for the mature crop.
- A revised Section F is needed. This Section F should propose the following revised tolerances: barley hay (0.8 ppm), oat hay (0.05 ppm), wheat forage (2.5 ppm), and wheat hay (0.7 ppm). The proposed 0.2 ppm tolerance for oat forage is appropriate.

### **Residue Chemistry Considerations**

A summary of the residue chemistry aspects of this tolerance petition has been prepared (Memo, D342084, D. Dotson, 4/17/2008). Reference may be made to this document for all aspects relating to analytical methods and residue data. Although the current tolerance petition is for the lifting of the feeding restrictions on the forage and hay of wheat, barley, and oats, HED has determined that animal commodity tolerances are not necessary, and the registrant does not need to submit a cattle feeding study. The dairy cattle dietary burden and the results of the goat metabolism study indicate that residues of thifensulfuron methyl could possibly occur in milk at

levels that are slightly above the LOQ when cattle are dosed at 10x the maximum dietary burden (MDB). In the goat metabolism study, residues in milk ranged up to 0.12 ppm when goats were dosed to a level of 28 ppm in the diet. This dosing level is 13x the dairy cattle MDB of 2.1 ppm. Prorating the milk residue level to a 1x feeding rate yields a residue value of 0.009 ppm. Prorating to a 10x feeding rate yields a residue value of 0.09 ppm. HED generally requests a feeding study if quantifiable residues are expected at a 10x or lower feeding rate. In this case, however, HED feels that the feeding study is not necessary for several reasons. The first reason is that the majority of the residue in the dairy cattle MDB comes from wheat forage. Although this commodity has a recommended tolerance of 2.5 ppm based on HED's Tolerance Generator for NAFTA-harmonized tolerances, the highest field trial value is 0.88 ppm and the mean and median residues are much lower (0.14 ppm and 0.02 ppm, respectively). At a 10x feeding rate, using these lower forage residues, residues in milk would be expected to be in the 0.001-0.04 ppm range which is less than, or close to, the quantitation limit. The second reason HED feels that the feeding study is not needed is that thifensulfuron methyl is a sulfonyl urea herbicide which has a very low application rate, and its residues decline rapidly in forage during the first week after application. Finally, the very low exposure and risk estimates resulting from the thifensulfuron methyl use (<1% of the population adjusted dose for the general U.S. population and all population subgroups in conservative dietary exposure analyses) also indicate that there is no need for a cattle feeding study at the present time. The MDBs for poultry and swine are the same as they were in the previous assessment. A poultry feeding study is also not required.

### Dietary Exposure and Risk

Acute and chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM-FCID, Version 2.03). The dietary exposure analyses and their results are discussed in Memo, D332686, D. Dotson, 12/8/2006. The DEEM-FCID Model uses food consumption data from the USDA's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and a supplemental children's survey conducted in 1998.

The acute dietary exposure analysis was performed for the population subgroup Females 13-49 only. This subgroup is the only one for which an acute dietary endpoint was identified. The analysis is based on tolerance level residues and 100% crop treated assumptions. No empirical processing factors were used. A DEEM (Version 7.81) default processing factor was used for corn syrup. For drinking water, the peak surface water concentration of 3.9 ppb was used. EFED generated this value with the FIRST Model. The population subgroup Females 13-49 utilizes 0.03% of the aPAD at the 95<sup>th</sup> percentile of exposure. This risk estimate is below HED's level of concern (i.e., 100% of the aPAD).

The chronic analysis is based on the same data for food commodities as were used in the acute analysis: tolerance level residues, 100% crop treated assumptions, and a default processing factor for corn syrup. For drinking water, the chronic surface water concentration of 1.5 ppb was used. EFED generated this value with the FIRST Model. The general U.S. population and all population subgroups have risk estimates that are below HED's level of concern (i.e., 100% of the cPAD). The most highly exposed population subgroup is Children 3-5 Years which utilizes

0.9% of the cPAD. The general U.S. population utilizes 0.4% of the cPAD. The results of the chronic dietary exposure analysis are given in Table 1, below.

<b>Table 1. Summary of Dietary Exposure and Risk for Thifensulfuron Methyl (Food and Drinking Water)</b>						
Population Subgroup*	Acute Dietary (95 <sup>th</sup> Percentile)		Chronic Dietary		Cancer	
	Dietary Exposure (mg/kg/day)	% aPAD	Dietary Exposure (mg/kg/day)	% cPAD	Dietary Exposure (mg/kg/day)	Risk
General U.S. Population	N/A	N/A	0.000284	<1	N/A	N/A
All Infants (< 1 year old)	N/A	N/A	0.000469	<1		
Children 1-2 years old	N/A	N/A	0.000601	<1		
Children 3-5 years old	N/A	N/A	<b>0.000621</b>	<b>&lt;1</b>		
Children 6-12 years old	N/A	N/A	0.000447	<1		
Youth 13-19 years old	N/A	N/A	0.000310	<1		
Adults 20-49 years old	N/A	N/A	0.000239	<1		
Adults 50+ years old	N/A	N/A	0.000175	<1		
Females 13-49 years old	0.000524	<1	0.000226	<1		

For all commodities in both the acute and chronic dietary exposure analyses, the assumption was made that 100% of the crop grown would be treated with thifensulfuron methyl.

There are no non-occupational/residential uses for thifensulfuron methyl. As a result, residential uses (including home and recreational uses, etc.) are not relevant to this assessment.

#### Aggregate Risk

For thifensulfuron methyl, acute aggregate risk consists of risks resulting from exposure to residues in food and drinking water only. The acute dietary exposure analysis included both food and drinking water; as a result, the acute aggregate risk assessment is equivalent to the acute dietary risk assessment. The only population subgroup for which an acute dietary endpoint was identified, Females 13-49, utilizes 0.03% of the aPAD at the 95<sup>th</sup> percentile of exposure. This risk estimate is below HED's level of concern (i.e., 100% of the aPAD).

As there are no residential uses for thifensulfuron methyl, short- and intermediate-term aggregate risk assessments are not required.

For thifensulfuron methyl, chronic aggregate risk consists of risks resulting from exposure to residues in food, drinking water, and residues resulting from residential applications. As there are no residential uses for thifensulfuron methyl, chronic aggregate risk consists of risks resulting from exposure to residues in food and drinking water alone. The chronic dietary exposure analysis included both food and drinking water; as a result, the chronic aggregate risk assessment is equivalent to the chronic dietary risk assessment. The general U.S. population and all population subgroups have risk estimates that are below HED's level of concern (i.e., 100% of the cPAD). The most highly exposed population subgroup is Children 3-5 Years which utilizes 0.9% of the cPAD. The general U.S. population utilizes 0.4% of the cPAD.

Thifensulfuron methyl was classified as not likely to be a human carcinogen. As a result, a cancer risk assessment is not required.

#### Tolerance Harmonization

There are no established or proposed Codex Maximum residue limits (MRLs) for residues of thifensulfuron methyl. Canada and Mexico have established MRLs for thifensulfuron methyl on several plant commodities. However, no Canadian or Mexican MRLs for thifensulfuron methyl have been proposed or established for the commodities being considered under this petition. Therefore, there are no harmonization issues with the proposed tolerances. The recommended tolerances associated with this tolerance petition are listed in Table 2, below.

<b>Table 2. Table of Recommended Tolerances for Thifensulfuron Methyl.</b>			
Commodity	Proposed Tolerance (ppm)	Recommended Tolerance (ppm)	Comments; <i>Correct Commodity Definition</i>
Barley, hay	0.7	0.8	Adequate residue data are available. Barley, hay
Oat, forage	0.2	0.2	Adequate residue data are available. Oat, forage
Oat, hay	2.0	0.05	Adequate residue data are available. Oat, hay
Wheat, forage	1.0	2.5	Adequate residue data are available. Wheat, forage
Wheat, hay	0.8	0.7	Adequate residue data are available. Wheat, hay



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